

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 19 June 2001 (19.06.01)	
International application No. PCT/GB00/03132	Applicant's or agent's file reference RRS/7269INT
International filing date (day/month/year) 11 August 2000 (11.08.00)	Priority date (day/month/year) 02 September 1999 (02.09.99)
Applicant WATERS, Russell, David	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 02 April 2001 (02.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference RRS/7269INT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/03132	International filing date (day/month/year) 11/08/2000	Priority date (day/month/year) 02/09/1999
International Patent Classification (IPC) or national classification and IPC A61B17/068		
Applicant BIOCOMPOSITES LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
 - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 02/04/2001	Date of completion of this report 09.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Schießl, W Telephone No. +49 89 2399 7436 

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03132

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-8 as originally filed

Claims, No.:

1-51 as received on 19/10/2001 with letter of 16/10/2001

Drawings, sheets:

1/2,2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03132

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 2-51.

because:

☒ the said international application, or the said claims Nos. 42-51 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 2-41 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 42-51.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03132

	No:	Claims	1
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1
Industrial applicability (IA)	Yes:	Claims	1
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Section III

- 1 The subject-matter of claim 1 is known from the prior art (cf. V, 2 below). The different combinations of features recited in the dependent claims 2-41 do not clearly define the matter for which protection is sought (Article 6 PCT) and thus do not allow to identify "the claimed invention" in the sense of Article 33.1 PCT, on which a further opinion should be based.
- 2 Claims 42-51 relate to subject-matter mentioned in Rule 67.1(iv) PCT, in particular to method of surgical treatment of the human or animal body. Under terms of Article 34(4)(a)(i) PCT an International Preliminary Examining Authority is not required to carry out an examination of such claims.

Section V

- 1 Reference is made to the following document (D) cited in the International Search Report:

D1: WO 99 26544 A (BIONX) 3 June 1999 (1999-06-03)
- 2 Novelty (Article 33(2) PCT)

The subject-matter of claim 1 is not new, since document D1 discloses an apparatus for applying surgical fixation devices (p. 9, l. 10 to p. 14, l. 15, figs. 1, 3), the apparatus comprising device inserting means which includes guide means in the form of a passage (2) along which a surgical device (fastener) is moveable; and a supply means (4) including means (4a) for holding one or more surgical devices, the supply means being movably mounted to the distal end of the guide means such that in a first condition the supply means is aligned with the passage distal end such that a surgical device held by the holding means is moveable into the passage (p. 11, para. 2), wherein in a second condition (namely when the present fastener has been deployed without repositioning of the magazine) free access is allowed to the distal end for the insertion of a surgical tool (9) through the passage (p. 14, ll. 10-15; note that the presently defined second condition is not related to a movement of the supply means away from the first condition and

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03132

that the expression 'insertion of a surgical tool through the passage' covers the piston of the instrument capable of pushing a fastener into tissue (contrary to a **separate** tool extending through the passage of the apparatus as mentioned on p. 7, last para., of the application)), and thus all features of claim 1.

Section VII

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 is not mentioned in the description, nor is this document identified therein.

**REPLACED BY
ART 34 AMDT**Claims

1. Apparatus for applying surgical devices, the apparatus comprising device inserting means (12) which includes guide means in the form of a passage (14) along which a surgical device is moveable, the passage (14) comprising in use inner (16) and outer ends (22); and a supply means (46, 48, 50, 58, 66) including means (54,72) for holding one or more surgical devices, the supply means (46, 48, 50, 58, 66) being moveable relative to the inserting means (12) such that in a first condition the supply means (46, 48, 50, 58, 66) is aligned with the passage outer end (22) such that a surgical device held by the holding means (54,72) is moveable into the passage (14), and in a second condition free access is allowed to the outer end (22).
2. An apparatus according to claim 1 characterised in that the supply means (46, 48, 50, 58, 66) is releasably mountable on the inserting means (12).
3. An apparatus according to claims 1 or 2 characterised in that the supply means (46, 48, 50, 58, 66) is movably mountable on the inserting means (12).
4. An apparatus according to claim 3 characterised in that the supply means (46, 48, 50, 58) is rotatably mountable on the inserting means (12).
5. An apparatus according to claim 3 characterised in that the supply means (66) is slidably mountable on the inserting means (12).
6. An apparatus according to any of the preceding claims characterised in that the inserting means (12) comprises a support member (20, 64).
7. An apparatus according to claim 6 characterised in that the support member (20, 64) is manually engageable by a user.
8. An apparatus according to claims 6 or 7 characterised in that the support member (20, 64) is provided at or adjacent the passage outer end (22).

9. An apparatus according to any of claims 6 to 8 characterised in that the supply means (46, 48, 50, 58, 66) is mountable on the support member (20, 64).
10. An apparatus according to any of claims 6 to 9 characterised in that the passage (14) extends through the support member (20, 64).
11. An apparatus according to any of the preceding claims characterised in that the inner end (16) of the passage (14) is shaped to aid positioning.
12. An apparatus according to claim 11 characterised in that the inner end (16) of the passage (14) comprises one or more pointed parts (18).
13. An apparatus according to any of claims 6 to 12 when dependent on claim 6 characterised in that the support member (20) includes a pivot pin (26) upon which the supply means (46, 48, 50, 58) is pivotally mountable.
14. An apparatus according to claim 13 characterised in that the supply means (46, 48, 50, 58) is pivotally mountable about a hole (52) in the supply means (46, 48, 50, 58).
15. An apparatus according to any of claims 6 to 14 characterised in that the support member (20, 64) is generally in the form of a disc.
16. An apparatus according to claim 15 when dependent on claims 13 or 14 characterised in that the pivot pin (26) is spaced from the disc axis.
17. An apparatus according to claim 10 or any of claims 11 to 16 when dependent on claim 10 characterised in that the supply means (46, 48, 50, 58, 66) is mountable on the support member (20, 64) so as to at least generally overlie the outer end (22) of the passage (14).
18. An apparatus according to any of the preceding claims characterised in that the holding means comprises one or more first holes (54, 72).

19. An apparatus according to claim 18 characterised in that a surgical device is wholly locatable in the first hole or holes (54,72) with the or each first hole (54,72) selectively alignable with the outer end (22) of the passage (14) to permit transfer of the device into the passage (14).

20. An apparatus according to claims 18 or 19 characterised in that a plurality of first holes (54) are provided in the supply means (46, 48, 50, 58, 66).

21. An apparatus according to any of claims 18 to 20 characterised in that the first hole or holes (54) has substantially the same diameter as the internal diameter of the passage (14).

22. An apparatus according to claim 4 or any of claims 6 to 21 when dependent on claim 4 characterised in that the supply means comprises a disc (46,48,50,58).

23. An apparatus according to claim 4 or any of claims 6 to 22 when dependent on claim 4 characterised in that the supply means (46, 48, 50, 58) is shaped to facilitate manual turning thereof.

24. An apparatus according to claim 23 characterised in that the supply means (58) comprises a plurality of lobes (62) surrounding an axis.

25. An apparatus according to claim 24 characterised in that a first hole (54) is provided in at least some of the lobes (62).

26. An apparatus according to claims 24 or 25 characterised in that at least some of the lobes (62) are spaced apart to define recesses (56) therebetween.

27. An apparatus according to any of the preceding claims characterised in that one or more second holes and/or recesses (56) are provided in the supply means (46, 48, 50, 58) through which second hole or holes or recesses (56) free

access is provided to the outer end (22) of the passage (14).

28. An apparatus according to claim 5 or any of claims 6 to 12 or 17 to 21 when dependent on claim 5 characterised in that the supply means (66) is slidably mountable on the support member (64).

29. An apparatus according to claim 28 characterised in that the support member (64) comprises a track (70) along which the supply means (66) is slidable.

30. An apparatus according to any of the preceding claims characterised in that the apparatus comprises a pushing means (28), engageable with a surgical device in the passage (14) to push the device therealong.

31. An apparatus according to claim 30 characterised in that the pushing means (28) comprises an elongate member (30).

32. An apparatus according to claim 31 characterised in that the elongate member (30) slidingly fits through the passage (14).

33. An apparatus according to claims 31 or 32 characterised in that the elongate member (30) has a handle part (34) on one end.

34. An apparatus according to any of claims 31 to 33 characterised in that the elongate member (30) is flexible.

35. An apparatus according to any of claims 30 to 34 characterised in that the end (32) of the pushing means (28) engageable with a surgical device is contoured.

36. An apparatus according to claim 35 characterised in that the end (32) of the pushing means (28) engageable with a surgical device is concave.

37. An apparatus according to any of the preceding claims characterised in that the apparatus comprises an incision means (36) extendible through the passage (14) for creating an incision.

38. An apparatus according to claim 37 characterised in that the incision means (36) comprises an elongate member (38), with an incision formation (44) at one end (42).

39. An apparatus according to claim 38 characterised in that the elongate member (38) has a handle (40) at the opposite end to the incision formation (44).

40. An apparatus according to claims 38 or 39 characterised in that the elongate member (38) is flexible.

41. A method of applying a surgical device into a body characterised in that the method comprises using apparatus according to any of the preceding claims.

42. A method according to claim 41 characterised in that the surgical device is initially located in the supply means (46, 48, 50, 58, 66).

43. A method according to claim 42 characterised in that the surgical device is located in the supply means (46, 48, 50, 58, 66) before the latter is mounted on the inserting means (12).

44. A method according to claims 42 or 43 characterised in that a plurality of surgical devices are mounted on the supply means (46, 48, 50, 58, 66).

45. A method according to any of claims 41 to 44 when dependent on any of claims 37 to 40 characterised in that an incision is initially made in the body using the incision means (36) extending through the guide means (14).

46. A method according to claim 45 characterised in that whilst the incision means (36) extends through the guide means (14), the holding means (46, 48, 50, 58, 66) is arranged such that a second hole or recess (56) therein overlies the guide means (14).

47. A method according to claim 46 characterised in that the incision means (36) freely extends through said second hole or recess (56).

48. A method according to any of claims 45 to 47 characterised in that following incision, the incision means (36) is removed.

49. A method according to claim 48 characterised in that following removal of the incision means (36) the supply means (40,48,50,58,66) is moved until a surgical device held therein overlies the guide means.

50. A method according to claim 49 characterised in that the device is subsequently urged into the guide means (14) and therealong subsequently into the body using a pushing means (28) according to any of claims 30 to 36.

51. Any novel subject matter or combination including novel subject matter disclosed herein, whether or not within the scope of or relating to the same invention as any of the preceding claims.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/03132

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/068

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 26544 A (BIONX) 3 June 1999 (1999-06-03) claim 10; figures 1,3,8	1
A	US 5 843 084 A (HART) 1 December 1998 (1998-12-01) figures 13-16	1
A	WO 99 22650 A (UNIVERSITY OF DUNDEE) 14 May 1999 (1999-05-14)	
A	EP 0 913 123 A (ARTHREX) 6 May 1999 (1999-05-06)	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

15 November 2000

Date of mailing of the international search report

24/11/2000

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/03132

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9926544	A	03-06-1999	US 6010513 A AU 1757399 A EP 1033939 A	04-01-2000 15-06-1999 13-09-2000
US 5843084	A	01-12-1998	AU 1055797 A WO 9718762 A	11-06-1997 29-05-1997
WO 9922650	A	14-05-1999	AU 9753798 A EP 1026994 A	24-05-1999 16-08-2000
EP 913123	A	06-05-1999	US 6056778 A JP 11299805 A	02-05-2000 02-11-1999